PRESOLICITATION NOTICE

MANUFACTURING AND CHARACTERIZATION SERVICES FOR VACCINES AND OTHER BIOLOGICS FOR INFECTIOUS DISEASES

RFP-NIAID-DMID-NIHAI2017089

Type of Requirement

☐ New Requirement

☒ Re-competition *(Contract/Task Order No.: HHSN272201200005I)*

☐ Expansion of *(Contract/Task Order/RFP No.:_____)*

Place of Performance

☒ Place of performance is unknown at this time

☐ Place of performance is known. Address or general location:_____

Recompetition

Advanced Bioscience Laboratories (ABL)

9800 Medical Center Drive

Rockville, MD 20850

800-225-5600

Contracting Office Address

Department of Health and Human Services, National Institutes of Health, National Institutes of Allergy and Infectious Diseases, Office of Acquisitions, 5601 Fishers Lane, MSC 9821, Bethesda, MD, 20892-9821

Duration of contract: 7 year ordering period and 10 year completion.

If Options will be included, describe Options N/A

Anticipated award date: May 1, 2018

Presolicitation Notice Information

Introduction

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), of the Department of Health and Human Services (DHHS) supports research related to the basic understanding of microbiology and immunology leading to the development of vaccines, therapeutics, and medical diagnostics for the prevention, treatment, and diagnosis of infectious and immune-mediated diseases. The NIAID, Division of Microbiology and Infectious Diseases (DMID), has a requirement for a product development-oriented program to provide preclinical development support for multiple vaccine and biologic candidates that emerge from academia, the private sector, or other sources. These services are intended to help a wide variety of investigators in a number of scientific areas obtain critical data needed to acquire additional funding, gain prospective partnerships (either for further development or to support Phase I/II trials), fulfill regulatory requirements, and support Phase I/II clinical studies. While the overall suite of services provided is comprehensive, the intent is to provide individual services on a case-by-case basis for a diverse collection of product candidates, rather than carry a single product candidate through an entire preclinical development pathway.

Description

The purpose of this solicitation is to support a suite of services that encompasses the activities commonly associated with product construction, process development, manufacture, and characterization of vaccine and biologic products for infectious diseases. These services will include support of early research and development projects through the product development process and includes manufacture of Phase I/II clinical material of quality sufficient for inclusion in Investigational New Drug (INDs) applications and/or Biologic License Applications (BLAs). NIAID recognizes that to obtain the full spectrum of expertise or facilities required to perform all activities set forth in this solicitation, individual organizations will likely need the expertise and resources of other organizations or persons through consortium agreements, partnerships, subcontracts, and/or consultants. The Offeror shall be responsible for ALL work performed and shall be responsible for project planning, initiation, implementation, management and communication; evaluation, selection, and management of subcontractors; and for all deliverables specified in this contract and each awarded Task Order.

This IDIQ will be administered and used primarily to support NIAID initiatives that help DMID accomplish its mission, respond to changing priorities as scientific and public health needs shift, rapidly

respond to public health emergencies and new disease threats, and improve surge capabilities. The Contractor shall provide NIAID with a broad and flexible range of manufacturing and characterization services for vaccines and other biologics that support preclinical, nonclinical, and clinical studies for promising products when such products emerge from investigator-initiated research studies or other sources identified by NIAID Program staff. The Contractor shall also provide appropriate documentation and support primarily for pre-IND, IND, and BLA submissions. These tasks shall be conducted in accordance with quality oversight that is appropriate to the phase of the specific task and within all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions. These quality regulations at a minimum include current Good Laboratory Practices (GLP) and cGMP [21 CFR Parts -11, -58, -210, -211, -600].

These capabilities may also support vaccines or other biological products that are intended for use in animals that constitute a disease reservoir for, or other disease threat from, a pathogen that has public health significance. Support for efforts associated with zoonotic diseases may be considered on a case-by-case basis dependent on adequate justification for Public Health considerations. In addition, efforts to provide limited support outside of Phase I/II clinical trials may also be considered on a case-by-case basis.

For the purposes of this contract, the following definitions shall apply:

- **Vaccine** – An antigenic preparation used to render an organism immune to an infectious disease by inducing or increasing immunity for prophylaxis and/or therapy, or eliciting immune-based responses that interrupt pathogenesis. Vaccine products include but are not limited to synthetic peptides, recombinant proteins, nucleic acids, viral-like particles, vector-based vaccines, as well as live, modified, and/or attenuated bacteria, viruses, parasites, and other organisms.

- **Vaccine Component** – Any substance or device that maintains, stabilizes, or enhances a vaccine's activity or ability to invoke an immune response. Vaccine components include, but are not limited to, adjuvants to increase immunogenicity, excipients to increase stability, and delivery systems including novel dosage forms and devices.

- **Other Biologic** – Therapeutic preparations made from living organisms or the components of living organisms and are most likely regulated by CBER. Biologics include but are not limited to allergenics; antitoxins; blood and blood products; cellular and gene therapy products. For the purposes of this contract, challenge material for non-clinical, preclinical, and clinical trials will also be included in the definition of biologics. Other biologics will include BSL-2, BSL-3, and BSL-4 material.

- **Reagent** – Materials required to manufacture and test vaccines, vaccine components, and other biologics in support of product release and characterization Reagents include, but are not limited to, assay components such as polyclonal and monoclonal antibodies, receptors, and cell lines; manufacturing reagents such as affinity resins, product specific components

such as conjugation reagents, and adjuvant specific reagents; and reagents required for potency, pre-clinical, and non-clinical assays.

The services shall be directed at the following:

- diseases caused by pathogens and toxins on the NIAID Category A, B, and C Priority Pathogens list (http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/Pages/CatA.aspx)
- emerging and re-emerging infectious diseases;
- antimicrobial resistant and multi drug resistant infections;
- other bacterial infections;
- fungal infections;
- viral infections; and
- parasitic diseases.

The Contractor shall be required to carry out the Scope and Activities defined in the following five Task Areas. Task Orders may address one Task Area or multiple Task Areas. Institute Contracting Officer's Representative (COR) and designees will collaborate with the Contractor in all awarded Task Orders. Technical Requirements will be defined in the individual Task Areas.

The Technical Requirements have been assembled into the following Task Areas:

Task Area A – Administrative and Technical Management Including Workshops

Task Area B – Product Development Plans and other Feasibility Studies

Task Area C – Product Screening, Optimization, Construction, and Process Development

Task Area D – Product Manufacture under cGMP in Support of Phase I/II Clinical Studies

Task Area E – Quality and Regulatory Management and Support Including Audits

NIAID anticipates awarding a single IDIQ contract that provides a guaranteed minimum award to the organization or consortium that best meets the overall qualifications needed to fulfill the technical requirements of this solicitation. Sample Task Orders are provided in the RFP solely to evaluate offeror responses and capabilities. Task Orders for specific tasks will be issued after award of the Parent Contract.

Assume responsibility for the following list of activities which represents a yearly estimate of tasks the Offerors should assume to perform each year under the contract.

Task Orders	Title	Estimated No. of Awards/year
A	Administrative and Technical Management Including Workshops	1
B	Product Development Plans and other Feasibility Studies	5
C	Product Screening, Optimization, Construction, and Process Development	4
D	cGMP in Support of Phase I/II Clinical Studies for MCBs	3
D	cGMP in Support of Phase I/II Clinical Studies for Bulk Drug Substance and Final Drug Product	1
E	Quality and Regulatory Management and Support Including Audits	2

Assume that the period of performance of task orders may range from one year to multiple years.

Any responsible offeror may submit a proposal which will be considered by the Agency. This RFP will be available electronically on or before March 1, 2017, and may be accessed through FedBizOpps http://www.fedbizopps.gov/. This notice does not commit the Government to award a contract or Task Order. No collect calls will be accepted. No facsimile transmissions will be accepted.

For this solicitation, the NIAID requires proposals to be submitted online via the NIAID electronic Contract Proposal Submission (eCPS) website. Submission of proposals by facsimile or e-mail is not acceptable.

For directions on using eCPS, go to the website https://ecps.niaid.nih.gov and then click on "How to Submit."